HFI 35 2/19/98

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District
19900 MacArthur Boulevard Suite 300
Irvine, California 92612-2445
Telephone (714) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

February 12, 1998 WL18-8

Mr. Gary Smith
President
Ophthalmic International
16929 E. Enterprise Drive #202
Fountain Hills, AZ 85268

Dear Mr. Smith:

During an inspection of your firm conducted between November 25 to December 11, 1997, our investigators determined that your firm distributed two vacuum fixation devices with suction rings to the Arizona Glaucoma Institute, 8049 North 85th Way, Scottsdale, Arizona for use in treating patients with glaucoma using a pneumatic trabeculoplasty (PNT) procedure. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your vacuum fixation devices are adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval (PMA) in effect pursuant to Section 515(a) or approved applications for investigational device exemption under Section 520(g).

Your vacuum fixation devices are also misbranded within the meaning of Section 502(o) in that a notice or other information respecting the devices was not provided to the FDA as required by Section 510(k) of the Act. In this regard, please note that your vacuum fixation device used to perform pneumatic trabeculoplasty is not a "fixation device", is intended for use as a target for the patient during ophthalmological examination. Your vacuum fixation device is different in design and is intended to be used to decrease the intraocular pressure of patients with glaucoma. It is not exempt from the premarket notification requirements, and requires a 510(k) application.

You have also suggested that the vacuum fixation device which your firm manufactures and distributes may have been cleared under a premarket notification submission for a keratome made by another firm, SCMD, Ltd. Please be advised that a new premarket notification submission would be required, even if SCMD, Ltd. were to manufacture and distribute the vacuum fixation device, because the use of the device for the treatment of glaucoma is a major change in intended use [21 CFR 807.81(a)(3)(ii)]. The Keratome is intended to be used to shave tissue from sections of the cornea for lamellar (partial thickness) transplant. This letter is also to notify you that, in accordance with 21 CFR 812.20(a), you are required to submit an investigational device exemption (IDE) application to FDA and obtain FDA approval of the application before beginning an investigation of the device for the treatment of glaucoma. You are also advised that the sponsors of investigations,

investigators, or any persons acting for or on behalf of a sponsor or an investigator may not promote or test market an investigational device, or represent that it is safe of effective for the purpose for which it is being investigated [21 CFR 812.7(a) and (d)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to assure that each of the noted violations has been corrected. This includes that actions you have taken or plan to take to address previously distributed products (e.g., the units at Arizona Glaucoma Institute).

Your response should also include an explanation of the specific steps taken to prevent the recurrence of similar violations. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92715-2445

Sincerely,

Elaine C. Messa
District Director

DER/jm

cc: Leo Bores, M.D.
Medical Director
Arizona Glaucoma Institute
8049 N. 85th Way
Scottsdale, AZ 85258

George Richard Smith
President
Arizona Glaucoma Institute
8049 N. 85th Way
Scottsdale, AZ 85258